From epa-pest@valley.rtpnc.epa.gov
X-Envelope-From: epa-pest@valley.rtpnc.epa.gov
Received: from valley.rtpnc.epa.gov by epamail.epa.gov (PMDF V5.1-8 #22480)
with ESMTP id <0EITXBU4K00AO2@epamail.epa.gov>; Wed,
29 Oct 1997 15:09:33 -0500 (EST)
Received: from valley (valley [134.67.208.16])
by valley.rtpnc.epa.gov (8.8.7/8.8.0) with SMTP id PAA07012; Wed,
29 Oct 1997 15:13:18 -0500 (EST)
Date: Wed, 29 Oct 1997 15:13:18 -0500 (EST)
From: envsubset@epamail.epa.gov
Subject: Ferric Phosphate; Establishment of an Exemption
Sender: epa-pest@valley.rtpnc.epa.gov
To: Multiple recipients of list <epa-pest@valley.rtpnc.epa.gov>
Errors-to: envsubset@epamail.epa.gov
Reply-to: epa-pest@valley.rtpnc.epa.gov
Message-id: <9710291657.AA29106@mountain.epa.gov>
Precedence: bulk
Originator: epa-pest@unixmail.rtpnc.epa.gov
X-Comment: U.S. EPA FEDERAL REGISTER PESTICIDE documents
X-Listprocessor-version: 6.0c -- ListProcessor by Anastasios Kotsikonas

[Federal Register: October 29, 1997 (Volume 62, Number 209)]
[Rules and Regulations]
[Page 56102-56105]
>From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr29oc97-29]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300564; FRL-5749-2]
RIN 2070-AB78

Ferric Phosphate; Establishment of an Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final Rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of ferric phosphate, when used as a molluscicide in or on all food commodities. W. Neudorff GmbH KG submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requesting the exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of this molluscicide in or on all food commodities.

DATES: This regulation is effective on October 29, 1997. Objections and requests for hearings must be received by December 29, 1997.
ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300564], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ``Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300564], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental

[[Page 56103]]

Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300564]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Sheryl K. Reilly, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location, telephone number, and e-mail address: CS1 Rm. 5-W31, 2800 Crystal Drive, Arlington, VA, 703-308-8265, e-mail: reilly.sheryl@epamail.epa.gov.
SUPPLEMENTARY INFORMATION: W. Neudorff GmbH KG, c/o Walter G. Telarek, PC, 1008 Riva Ridge Drive, Great Falls, VA, has requested in pesticide petition PP 7F4804 the establishment of an exemption from the requirement of a tolerance for residues of the molluscicide iron (ferric) phosphate. A notice of filing (FRL-5721-6) was published in the Federal Register (62 FR 32331-32336) on June 13, 1997, and the notice announced that the comment period would end on July 13, 1997; no comments were received.

This exemption from the requirement of a tolerance will permit the marketing of raw agricultural commodities when treated in accordance with EPA Reg No. 67702-3, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136).

The data submitted in the petition and all other relevant material have been evaluated. The following is a summary of EPA's findings

regarding this petition.

I. Product Identity

NEU 1165M Slug and Snail Bait (EPA file symbol No. 067702-G) is the first pesticide product containing the active ingredient ferric phosphate (FePO<INF>4</INF>, CAS# 11045-86-0). The product contains the active ingredient at a concentration of 1% incorporated into a solid matrix, which is odorless, and has a white-to-buff color.

II. Risk Assessment and Statutory Findings

New section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ``safe.'' Section 408(c)(2)(ii) defines ``safe'' to mean that ``there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ``ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue***.'' EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the scientific data and other relevant information in support of this action and considered its validity, completeness, reliability, and relationship to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A battery of acute toxicity studies place NEU 1165M Slug and Snail Bait in the following Toxicity Categories: Acute Oral (Toxicity Category IV); Acute Dermal (Toxicity Category IV; Primary Eye Irritation (Toxicity Category III); and Primary Dermal Irritation (Toxicity Category IV). (MRIDs 440427-04,-05, -06, and -07)

Data waivers were requested for acute inhalation toxicity, dermal sensitization, genotoxicity, reproductive and developmental toxicity, subchronic (90-day) oral toxicity, and chronic toxicity. The waivers were accepted based on the long history of use of iron and iron salts by humans without any indication of deleterious effects, and on the following:

The toxicity of ferric phosphate is low; ferric phosphate occurs naturally as a mineral, and is added to food, such as bread, for

nutritional fortification. Iron is an essential nutrient for humans and all other vertebrates; the average human diet contains 10-15 mg of iron a day. Ferric phosphate is also sometimes used as a fertilizer. In addition, iron is found in abundance in nature; the low water-solubility of ferric phosphate limits its absorption across the intestinal epithelium.

IV. Residue Chemistry

A waiver was requested and granted for magnitude of the residue anticipated at the time of harvest and method used to determine the residue data requirements based on ferric phosphate's (1) low toxicity, (2) natural occurrence, (3) abundance in the environment, (4) widespread use as human nutrient and dietary supplements and in infant formula, (5) status at FDA as ``generally recognized as safe'' (GRAS), and (6) data available in the open literature.

V. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. Dietary exposure. Dietary exposure of ferric phosphate via food or water exists due to its use as a nutritional supplement and its ubiquitous presence in nature. Residues from use of the biochemical pesticide, ferric phosphate, will not significantly add to the current dietary exposures.

2. Non-dietary, non-occupational exposure. Increased non-dietary exposure of ferric phosphate via non-commercial greenhouse, home lawn and garden or ornamental use will be minimal. Exposure by the inhalation route would be non-existent because

[[Page 56104]]

ferric phosphate is not volatile and the formulation of the product is a solid matrix of non-respirable size. In summary, the potential aggregate exposure, derived from non-dietary and non-occupational exposure should be minimal.

VI. Cumulative Effects

Ferric phosphate has a very low toxicity to humans. Because of its low toxicity, low rate of application, and use patterns, the Agency believes that there is no reason to expect any cumulative effects from ferric phosphate and other substances.

VII. Endocrine Disruptors

The Agency has no information to suggest that ferric phosphate has any effect on the immune and endocrine systems. The Agency is not

requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. Nevertheless, the above discussion on exposure from all sources combined with the low toxicity of ferric phosphate would indicate such testing would not be necessary.

VIII. Safety Determination for U.S. Population, Infants and Children

Based on the information discussed above, EPA concludes that there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of ferric phosphate. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, the toxicity of ferric phosphate to mammals is very low and under reasonably foreseeable circumstances it does not pose a risk.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that ferric phosphate is practically non-toxic to mammals, including infants and children, and, thus, there are no threshold effects, and EPA has not used a margin of exposure (safety) approach to assess the safety of ferric phosphate. As a result, the provision requiring an additional margin of exposure (safety) does not apply.

IX. Other Considerations

1. Analytical method. The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for ferric phosphate residues.

2. Codex maximum residue level. There are no CODEX tolerances nor international tolerance exemptions for ferric phosphate at this time.

X. Conclusion

Based on the information discussed above, EPA establishes an exemption from the requirement of a tolerance pursuant to FFDCA section 408(j)(3) for ferric phosphate.

This exemption from the requirement of a tolerance will be revoked if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

XI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ``object'' to a tolerance exemption regulation issued by EPA under new section 408(e) as was provided in the old section 408. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person adversely affected by this regulation may, on or before December 29, 1997, file written objections to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

XII. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300564] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which

[[Page 56105]]

will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ``ADDRESSES'' at the beginning of this document.

XIII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629), February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerance exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

XIV. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted a report containing this rule and other required information to the U.S.

Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This is not a major rule as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 21, 1997.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371

2. Section 180.1191 is added to subpart D to read as follows:

Sec. 180.1191 Ferric phosphate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide, ferric phosphate (FePO<INF>4</INF>, CAS No. 11045-86-0) in or on all food commodities.

[FR Doc. 97-28657 Filed 10-28-97; 8:45 am]
BILLING CODE 6560-50-F

United States
Environmental Protection
Agency

Office of Prevention,
Pesticides
and Toxic Substances
(7501C)

PESTICIDE FACT SHEET

Name of Pesticide Product: Neu 1165M Slug and Snail Bait
Name of Chemical: Iron (Ferric) Phosphate
Reason for Issuance: Registration
Date Issued: AUG 14 1997
Fact Sheet Number:

1. DESCRIPTION OF THE CHEMICAL

Generic Name(s) of the Active Ingredient(s):	Iron (ferric) orthophosphate, iron (ferric) phosphate ($FePO_4 \cdot 2H_2O$)
OPP Chemical Codes	34903
Year of Initial Registration:	1997
Pesticide Type:	Biochemical molluscicide
U.S. and Foreign Producers:	W. Neudorff GmbH KG An der Muhle 3 D-31860 Emmerthal, Germany

2. USE SITES, APPLICATION TIMING & TARGET PESTS

Iron phosphate is to be used as the pesticidal active ingredient in a slug and snail bait formulation, on terrestrial, noncommercial food crops (vegetables, berries, fruit trees including citrus), domestic outdoor ornamental, lawn and garden use, and noncommercial greenhouses. The bait granules, which are noodle-like in appearance, are scattered on the soil around or near the plants to be protected. The soil to be treated should be moist, but with little or no standing water, and evening is the best time of day to apply, as slugs and snails travel

and feed mostly by night or early morning. For terrestrial, noncommercial food crops, domestic outdoor ornamental, lawn and garden use, the bait should be evenly applied at a rate of 1 lb. per 1,000 square feet (0.15 oz., or about 1 level teaspoon per square yard). For noncommercial greenhouse use, the slug and snail bait granules should be applied at a rate of ½ teaspoon per 9 inch. The bait should be reapplied as it is consumed or at least every two weeks, or when the area is heavily watered or after periods of heavy rain.

3. **SCIENCE FINDINGS**

A. TOXICOLOGY: All toxicity data requirements have been satisfied for the purpose of the registration. The information submitted to support the acute toxicity requirements for iron phosphate indicate toxicity category IV for acute oral toxicity, category IV for acute dermal toxicity, category III for primary eye irritation, and category IV for primary dermal irritation. Acute inhalation, dermal sensitization, genotoxicity, immunotoxicity, developmental toxicity and subchronic (90 day) oral toxicity studies were waived because of iron phosphates' FDA GRAS (generally regarded as safe) status, the abundance of iron in nature, its low toxicity, its use as a nutritional supplement, and its low water-solubility, which would decrease its absorption across the intestinal epithelium.

B. HUMAN HEALTH EFFECTS:

No unreasonable adverse effects to human health are expected from the use of iron phosphate.

1. Risks Posed by Potential Dietary Exposure

The proposed use pattern for NEU 1165M Slug and Snail Bait will result in dietary exposure with possible residues on food grown in the home garden setting. However, in the absence of any toxicological endpoints, risk from the consumption of treated commodities is not expected for both the general population and infants and children. Acute exposure could occur from the proposed outdoor use sites, but would be very low because of the low applications rates. The application rate is 1 lb. per 1,000 square feet, with no maximum number of applications. No residue data were required since the use is for terrestrial, noncommercial food crops (vegetables, berries, fruit trees, including citrus),

domestic outdoor ornamentals, lawns, gardens, and noncommercial greenhouses.

2. Effects on Immune and Endocrine Systems

The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed three years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. However, BPPD has considered, among other relevant factors, available information concerning whether iron phosphate may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite of iron phosphate that acts as an "endocrine disrupter" or an immunotoxicant. Therefore, no adverse effects to the endocrine or immune systems are known or expected.

3. Risks Posed by Potential Residential, School or Daycare Exposure

No indoor residential, school or daycare uses currently appear on the label. The use sites are terrestrial, noncommercial food crops (vegetables, berries, fruit trees, including citrus), domestic outdoor ornamentals, lawns, gardens, and noncommercial greenhouses. Nondietary exposure to these sites could occur where children are present, but the health risk is expected to be minimal to nonexistent based on evaluations of the submitted studies and the low toxicity of iron salts.

4. Potential for the Transfer of the Pesticide to Drinking Water

Although the potential exists for a minimal amount of iron phosphate to enter ground water or other drinking water sources, phosphate has an extremely low solubility in water. Thus, the amount would, in all probability, be undetectable or more than several orders of magnitude lower than those levels considered necessary for safety. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to iron phosphate through

drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

A battery of acute toxicity/pathogenicity studies is considered sufficient by the Agency to perform a risk assessment for biochemical pesticides.

In considering health risk from iron phosphate, it is important to keep the ubiquitous nature of this mineral in mind. Despite decades of widespread use of iron as a nutritional supplement, there have been no confirmed reports of immediate or delayed allergic reactions with significant oral exposure.

6. Cumulative Exposure From Multiple Routes Including Dermal, Inhalation, and Oral

Oral exposure would only occur if the product itself is eaten. Since the acute oral toxicity study demonstrated no adverse effects, it is the Agency's opinion that exposure by the oral route should not pose a significant threat to human health.

Since the acute dermal toxicity and acute dermal irritation study demonstrated no adverse effects, it is the Agency's opinion that exposure to the skin should not pose a risk to health.

Exposure by the inhalation route would be nonexistent, due to the formulation of the substance, being of a noodle-like consistency. In addition, iron phosphate is not volatile. In summary, the potential aggregate exposure, derived from oral, dermal and inhalation exposure should be minimal.

C. **ECOLOGICAL EFFECTS**:

1. Ecological Effects Hazard Assessment

A number of ecological effects toxicology data requirements were waived based on the known lack of toxicity of iron

phosphate to birds, fish and non-target insects, its low solubility in water, conversion to less soluble form in the environment (soil), and its use pattern (soil application). An acute oral toxicity study in Bobwhite quail (NOEL & LD50 greater than 2000 mg/kg) indicated that iron phosphate was practically nontoxic to avian species. Based on these factors, the data requirements for the toxicity studies in Mallard duck, rainbow trout, freshwater invertebrates, and nontarget insect/honeybees are waived. It is likely that there will be exposure to ground-feeding nontarget insects and earthworms. Submitted studies involving ground beetles, rove beetles and earthworms demonstrated that the product will not affect these organisms at up to two times the maximum application rate.

2. Environmental Fate and Ground Water Data

Exposure assessments on this type of product (biochemical pesticide) are not performed unless human health or ecological effects issues arise in the toxicity studies for either of these disciplines (40 CFR §158.740(d)(2)(vi)). Since no endpoints of concern were identified, there is no requirement for environmental fate data.

3. Ecological Exposure and Risk Characterization

Exposure to daphnids and other aquatic invertebrates would not occur based on current label use directions. Exposure to honeybees is also not expected to occur, due to the composition of the end-use product (noodle-like material) and its use pattern (soil application). Nontarget insects, such as ground beetles and earthworms, could encounter the end-use product; however, in tests of rove beetles, ground beetles and earthworms, no effects were observed at up to twice the maximum application rate. Thus, the acute risk to aquatic invertebrates, nontarget insects, and earthworms is considered minimal to nonexistent.

4. DATA GAPS

There are no data gaps for this pesticide registration.

5. **Regulatory Actions**

A. **Unconditional Registration**

All data requirements are fulfilled and the Biopesticides and Pollution Prevention Division recommends unconditional registration of NEU 1165M Slug and Snail Bait, containing the new pesticidal active ingredient, iron (ferric) phosphate.

B. **Tolerance**

There is no tolerance or exemption from tolerance for the active ingredient, iron phosphate. A tolerance or exemption from tolerance is not applicable, due to the domestic, noncommercial uses of this product.

7. **CONTACT PERSON AT EPA** — **OFFICE LOCATION/TELEPHONE NUMBER**

Sheryl K. Reilly, Ph.D.
Regulatory Action Leader
Biopesticides and Pollution
Prevention Division (7501W)
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

5th Floor, Crystal Station I
2800 Crystal Drive
Arlington, VA 22202
(703) 308-8265

8. **DISCLAIMER:** The information in this Pesticide Fact Sheet is a summary only and is not to be used to satisfy data requirements for pesticide registration and reregistration. Contact the Regulatory Action Leader listed above for further information.

Iron Phosphate
(PC Code 34903)

Table of Contents

I. Executive Summary

A. IDENTITY

NEU 1165M Slug and Snail Bait (EPA File Symbol No. 67702-G) is the first product containing the active ingredient iron phosphate (PC Code 34903). The product contains the active ingredient at a concentration of 1% incorporated into a solid matrix, which is odorless and has a white-to-buff color, and noodle-like appearance.

B. USE/USAGE

The end-use involves spreading the bait granules on the soil around or near the plants to be protected, at a rate of approximately 1 lb. per 1,000 square feet (0.15 oz., or 1 level teaspoon per square yard). The bait should be scattered on the soil around the perimeter of domestic or non-commercial garden plots, at the base of the plants and between rows where slugs and snails are a problem. The product may be reapplied as it is consumed or at least every two weeks. The soil should be moist before application.

C. RISK ASSESSMENT

There is a reasonable certainty that no harm will result from aggregate exposure to NEU 1165M Slug and Snail Bait. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoints

No toxicological endpoints are identified.

b. Human Exposure

All data requirements have been fulfilled for the active ingredient. The toxicity of iron salts is low; doses < 20 mg/kg (computed as elemental iron) are considered nontoxic. Mild to moderate iron toxicity is seen with doses of 20-60 mg/kg, and severe iron toxicity and death are associated with doses of 200-300 mg/kg. Iron phosphate occurs naturally as a mineral, and is added to food, such as bread, for nutritional fortification. Iron is an essential nutrient for humans and all other vertebrates; the average human diet contains 10-15 mg of iron a day.

The submitted acute toxicity studies indicate Toxicity Category III for NEU 1165M Slug and Snail Bait for eye irritation potential. The acute oral toxicity,

dermal, and dermal irritation studies for NEU 1165M Slug and Snail Bait classified the product as Toxicity Category IV. Acute inhalation, dermal sensitization, genotoxicity, immunotoxicity, developmental toxicity and 90-day oral toxicity studies were waived because of its GRAS status, the abundance of iron in nature, its low toxicity, its use as a nutritional supplement, and its low water-solubility, which would decrease its absorption across the intestinal epithelium. Further, the nature of the inert ingredients is such that Toxicity Category IV can be assumed.

c. Risk Assessment

We have considered iron phosphate in light of the nine safety factors listed in the Food Quality Protection Act (FQPA) and have made a determination of reasonable certainty of no harm. In short, BPPD has not identified any subchronic, chronic, immune, endocrine, or nondietary cumulative exposure issues as they may affect infants and children and the general population.

2. Ecological Risk Assessment

a. Ecological Toxicity Endpoints

No unreasonable adverse ecological or environmental fate effects on avian, aquatic or other nontarget organisms were identified.

b. Ecological Exposure

Iron is one of the earth's most abundant elements, and it is immobilized at the pH range of 5-9. Runoff to aquatic systems is unlikely, since the parent compounds convert very rapidly to less soluble forms in the environment. Iron phosphate is insoluble in water, and therefore, exposure to aquatic species should be relatively low. Furthermore, the oxidized iron compounds bind tightly to soil under turf.

Due to the composition of the end-use product and its use pattern, there should be no significant honey bee exposure. There will likely be exposure to ground-feeding nontarget insects and earthworms. Submitted studies involving ground beetles, rove beetles and earthworms demonstrate that the product will not affect these organisms at up to two times the maximum application rate.

Because of its insolubility in water and the known lack of toxicity to birds and data submitted that demonstrated a lack of toxicity to nontarget insects and earthworms, waiver requests were approved for the acute avian dietary, freshwater fish, and freshwater invertebrates studies. A waiver was granted

for honeybees based on the lack of significant exposure due to the composition of the product and its use pattern.

c. Risk Assessment

No unreasonable adverse ecological or environmental fate effects were identified.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps.

II. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name: iron phosphate ($FePO_4 \cdot 2H_20$)

Trade and Other Names: NEU 1165M Slug and Snail Bait, iron orthophosphate, iron phosphate

CAS Registry Number: 10045-86-0

OPP Chemical Code: 34903

Basic Manufacturer: W. Neudorff GmbH KG
An der Muhle 3
D-31860 Emmerthal, Germany

B. USE PROFILE

The following is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Molluscicide

Use Sites: Terrestrial, noncommercial food crops (vegetables, berries, fruit trees, including citrus), domestic outdoor ornamental, lawn and garden use, and noncommercial greenhouses.

Target Pests: Slugs and snails.

Formulation Type : Bait/granular formulation

Method and Rates of Application: The slug bait granules should be scattered on the soil around or near the plants to be protected. Bait should be applied evenly at a rate of 1 lb. per 1,000 square feet (0.15 oz., or about 1 level teaspoon per square yard), and reapplied as the bait is consumed or at least every two weeks, or when the area is heavily watered or after periods of heavy rain.

All areas of infestation should be treated, especially the perimeter of garden plots, flower gardens, rockeries, hedges, dichondra lawns, citrus groves, ivy patches, and other ground cover.

For vegetables and berries, the bait should be scattered around the perimeter of the plot at approximately 1 lb. per 1,000 square feet, and if slugs or snails are inside the

rows, then the bait should be scattered on the soil around the base of the plants and between the rows.

For non-commercial fruit tree seedlings and ornamentals, the bait should be applied at 0.15 oz., or 1 level teaspoon, per square yard, in a six-inch circular band around the base of the plants to be protected. For older trees, the bait should be spread around the base of the tree at approximately 1 lb. per 1,000 square feet.

For non-commercial greenhouse use, the bait is applied at the rate of 1/2 teaspoon per 9 inch pot.

For domestic lawns, the bait is applied at approximately 1 lb. per 1,000 square feet.

Type of Treatment: Granular

Equipment: By hand or with a granular spreader.

Timing: Evening is the best time of day to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

Use Practice Limitations: NEU 1165M Slug and Snail Bait should be applied to moist soil, but with little or no standing water.

C. ESTIMATED USAGE

Yet to be used since these will be the first registered products.

D. DATA REQUIREMENTS

For NEU 1165M Slug and Snail Bait, the mammalian toxicology data requirements for the technical product have been fulfilled. Product analysis data requirements are adequately satisfied. All ecological effects data requirements for NEU 1165M Slug and Snail Bait have been adequately fulfilled. The data requirements for granting this registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on available information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of this chemical and recommends an unconditional registration of NEU 1165M Slug and Snail Bait, containing the new active ingredient, iron phosphate, for the proposed uses.

Safety factors from the Food Quality Protection Act of 1996 (FQPA) were considered. Given the low toxicity of iron phospbate, its ubiquity in the environment, and a history of safe use of iron phosphate as a nutritional supplement and food additive, a determination of

reasonable certainty of no harm for the general population as well as subgroups including infants and children was made.

E. REGULATORY HISTORY

This action registers the first pesticide product using iron phosphate as the active ingredient. In June, 1996, the Agency received an application from W. Neudorff GmbH KG to register one end-use product containing iron phosphate as the active pesticidal ingredient. A notice of receipt of the application for registration of iron phosphate as a new active ingredient was published in the ***Federal Register*** (61 FR 3287) on January 22, 1997, with a 30-day comment period. No comments were received as a result of this publication.

The registrant did not initially submit a petition for an exemption from the requirement of tolerance, based on the argument that the use pattern and nature of the active ingredient would not fall within the terrestrial food-crop general use pattern. The product is not applied directly or indirectly to growing crops, only around crops, and the registrant argued that due to the physical and chemical properties of iron, residues of this product will not occur in crops. However, the Health Effects Division (R. W. Cook memo, October 4, 1996) determined that based upon the proposed uses, this product would be considered a "food use" pesticide product, and thus be subject to regulation under FFDCA and FIFRA, as amended. The suggestion was made that if the use of the bait was clearly limited to home gardens (i.e., crops which would not move in commerce), then the product would not be subject to the tolerance or exemption from tolerance requirements of FFDCA and FIFRA, as amended.

The registrant submitted an amendment (OPP identifier number 248352) on November 27, 1996, requesting removal of food uses from the label, thereby eliminating the need for a tolerance or an exemption from the requirement for a tolerance.

A petition for exemption from the requirement of tolerance (PP 7F4804) was received December 16, 1996, and a notice of filing of this petition was published in the *Federal* ***Register*** (62 FR 32331-32336) on June 13, 1997. The registrant has indicated they will request an amendment to add the agricultural uses to their label after the comment period for the notice of filing has expired on July 13, 1997, barring any comments or objections from the public concerning an exemption from the requirement of a tolerance for iron phosphate when used on growing crops.

F. FOOD CLEARANCES/TOLERANCES

The use of NEU 1165M Slug and Snail Bait is limited to home gardens, i.e., crops which would not move in commerce. Therefore, a tolerance establishment/exemption is not an issue for the proposed uses.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for NEU 1165M Slug and Snail Bait are satisfied.

1. Product Identity and Mode of Action

NEU 1165M Slug and Snail Bait (EPA File Symbol No. 067702-G) is the first pesticide product containing the active ingredient iron phosphate (PC Code 34903). The product contains the active ingredient at a concentration of 1% incorporated into a solid matrix, which is odorless and has a white-to-buff color, noodle-like appearance.

The bait is a strong attractant to slugs and snails, which consume the bait product. The iron phosphate accumulates in the calcium spherules of their digestive glands; this interferes with calcium metabolism, and in turn, disrupts feeding and mucus production. The slugs and snails will stop feeding, and death due to starvation will occur three-to-six days later.

2. Food Clearances/Tolerances

The use of NEU 1165M Slug and Snail Bait is limited to home gardens, i.e., crops which would be sold commercially. Therefore, a tolerance establishment/exemption is not an issue for the proposed uses.

Safety factors from FQPA were evaluated. BPPD has considered, among other relevant factors, available information concerning the aggregate exposure levels of consumers and major identifiable subgroups of consumers to the pesticide chemical residue and to other related substances. These considerations include exposure from nonoccupational sources. Given the low toxicity of iron phosphate, and a history of safe use of this and other iron salts, a determination of reasonable certainty of no harm for the general population as well as subgroups including infants and children was made.

3. Physical and Chemical Properties Assessment

Chemistry data that support the registration of NEU 1165M Slug and Snail Bait are summarized in tables 1 and 2, below. Boiling point, vapor pressure, pH, and octanol/water partition coefficient data requirements were waived, based on the general abundance in the environment of iron salts, their low toxicity, occurrence in the normal diet, use as a dietary food supplement, and GRAS status.

Table 1

Guideline		Classification	
151-17	Physical Properties	A	
63-2	Color	A	white to buff
63-3	Physical State	A	solid or dry powder
63-4	Odor	A	odorless
63-5	Melting Point	N/A	loses H_2O at >140°C and degrades to Fe_2O_3
63-6	Boiling Point	Waived	
63-7	Density	A	2.87 MI 12: 4074
63-8	Solubility	N/A	insoluble
63-9	Vapor Pressure	Waived	does not volatilize
63-10	Dissociation Constant	N/A	does not dissolve in water
63-11	Octanol / Water Partition Coefficient	Waived	does not dissolve in water
63-12	pH (when ground and diluted)	N/A	not miscible with water
63-13	Stability	N/A	stable
63-14	Oxidizing or Reducing	N/A	
63-15	Flammability (Flashpoint)	N/A	
63-16	Explodability	N/A	
63-17	Storage Stability	A	no change after 1 year
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	not an emulsifiable liquid
63-20	Corrosion Characteristics	N/A	
63-21	Dielectric Breakdown Voltage	N/A	for products used near electrical equipment

A= Acceptable N/A = Not Applicable, end use product in solid matrix

Table 2

Guideline	Study	Results	MRID #
151-10	Product Identity	The end-use product contains the a.i., $FePO_4$, in a solid, noodle-like material.	440706-01
151-11	Manufacturing Process	Using materials obtained from suppliers that are nonreacting, manufacturing is carried out batchwise in a mixer used to mix dry powders and water. The product is extruded to form short, noodle-like granules, which is stored in a nonreactive container or packaged for eventual distribution.	440706-01
151-12	Formation of Impurities	N/A. Essentially pure (99.9%) $FePO_4 \cdot 2H_20$; trace metals <100 ppm	440706-01
151-13	Analysis of Samples	Acceptable study	440427-01
151-15	Certification of Limits	Limits are acceptable	440427-01
151-16	Validation of Methods Analysis	Acceptable study	440427-01
151-17	Physical & Chemical Properties/Storage Stability	Storage: stable for 1 year, room temp. other properties (pH, etc.) in table above	440427-02

B. HUMAN HEALTH ASSESSMENT

Mammalian toxicology data have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.690 for biochemical pesticides for non-commercial food, non-food, domestic outdoor uses.

1. Toxicology Assessment

No toxicological endpoints are identified. All data requirements have been fulfilled for the active ingredient. Iron phosphate occurs naturally as a mineral, and is added to food, such as bread, for nutritional fortification. Iron is an essential nutrient for humans and all other vertebrates; the average human diet contains 10-15 mg of iron a day.

a. Acute Toxicity

The required acute mammalian toxicology studies or requests for waivers of data have been submitted. The submitted acute toxicity studies indicate Toxicity Category III for NEU 1165M Slug and Snail Bait for eye irritation potential. The acute oral toxicity, dermal, and dermal irritation studies for NEU 1165M Slug and Snail Bait classifed the product as Toxicity Category IV. Acute inhalation and dermal sensitization were waived because the abundance of iron and iron salts in nature, its low toxicity, its use as a nutritional supplement, and the low water-solubility of iron phosphate, which would decrease its absorption across the intestinal epithelium. Further, the nature of the inert ingredients is such that Toxicity Category IV can be assumed.

b. Subchronic and Chronic Tests

Immune response, teratogenicity, mutagenicity and subchronic oral toxicity were not required because of the abundance of iron in nature, its GRAS status, its low toxicity, its use as a nutritional supplement, and the low water-solubility of iron phosphate, which would limit its absorption across the intestinal epithelium. The following table summarizes tbe acute toxicity data submitted for NEU 1165M Slug and Snail Bait:

Table 3

Guideline	STUDY	RESULTS	MRID #
152-10	Acute Oral Toxicity	Toxicity Category IV	440427-04
152-11	Acute Dermal Toxicity	Toxicity Category IV	440427-05
152-12	Acute Inhalation	Waived	
152-13	Primary Eye Irritation	Toxicity Category III	440427-06
152-14	Primary Dermal Irritation	Toxicity Category IV	440427-07
152-15	Hypersensitivity	Waived	
	Literature Review- Iron Phosphate Toxicity	Acute toxicity of iron salts is low, and requires relatively large doses to induce effects. Initial symptoms include vomiting, hemorrhagic gastritis, and diarrhea. Hematemesis, perforation of the GI tract, lethargy, coma, convulsions, pulmonary edema, cyanosis, and/or vascular collapse may occur 12-24 hours later and death may result.	440578-01

c. Effects on the Immune and Endocrine Systems

The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress has allowed three years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. However, BPPD has considered, among other relevant factors, available information concerning whether iron phosphate may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite of iron phosphate that acts as an "endocrine disrupter" or an immunotoxicant. Therefore, no adverse effects to the endocrine or immune systems are known or expected.

2. Dietary Exposure and Risk Characterization

The proposed use pattern for NEU 1165M Slug and Snail Bait will result in dietary exposure with possible residues on food grown in the home garden setting. However, in the absence of any toxicological endpoints, risk from the consumption of treated commodities is not expected for both the general population and infants and children. Acute exposure could occur from the proposed outdoor use sites, but would be very low because of the low applications rates. The application rate is 1 lb. per 1,000 square feet, with no maximum number of applications. No residue data were required since the use is for terrestrial, non-commercial food crops (vegetables, berries, fruit trees, including citrus), domestic outdoor ornamentals, lawns, gardens, and non-commercial greenhouses.

3. Occupational, Residential, School and Daycare Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

Based on the application methods listed on the product label, the potential for dermal and eye exposures for pesticide handlers exists. Because of the domestic, nonagricultural use of the product, worker exposure data (i.e., occupational exposure data) to the active ingredient is not required at this time. However, due to the primary eye irritation response (Toxicity Category III for NEU 1165M Slug and Snail Bait), the Agency is requiring appropriate Signal Word and Precautionary Statements as indicated in Section IV C, under Labeling Rationale. It is the Agency's position that these exposures and subsequent risks are negligible because: (1) the product labeling stipulated in Section IV C will adequately mitigate the risks to handlers of the product; and (2) the toxicity of iron phosphate is very low in humans and animals. The risks are expected to be minimal based on evaluations of submitted acute toxicity tests and the ubiquity in nature and low toxicity of iron salts.

b. Residential, School and Daycare Exposure and Risk Characterization

No indoor residential, school or daycare uses currently appear on the label. The use sites are terrestrial, non-commercial food crops (vegetables, berries, fruit trees, including citrus), domestic outdoor ornamentals, lawns, gardens, and non-commercial greenhouses. Nondietary exposure to these sites could occur where children are present, but the health risk is expected to be minimal to nonexistent based on evaluations of the submitted studies and the low toxicity of iron salts.

4. Drinking Water Exposure and Risk Characterization

Although the potential exists for a minimal amount of iron phosphate to enter ground water or other drinking water sources, phosphate has an extremely low solubility in

water. Thus, the amount would, in all probability, be undetectable or more than several orders of magnitude lower than those levels considered necessary for safety. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to iron phosphate through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

A battery of acute toxicity/pathogenicity studies is considered sufficient by the Agency to perform a risk assessment for biochemical pesticides.

In considering health risk from iron phosphate, it is important to keep the ubiquitous nature of this mineral in mind. Despite decades of widespread use of iron as a nutritional supplement, there have been no confirmed reports of immediate or delayed allergic reactions with significant oral exposure.

6. Aggregate Exposure from Multiple Routes Including Oral, Dermal and Inhalation

Oral exposure would only occur if the product itself is eaten. Since the acute oral toxicity study demonstrated no adverse effects, it is the Agency's opinion that exposure by the oral route should not pose a significant threat to human health.

Since the acute dermal toxicity and acute dermal irritation study demonstrated no adverse effects, it is the Agency's opinion that exposure to the skin should not pose a risk to health.

Exposure by the inhalation route would be nonexistent, due to the formulation of the substance, being of a noodle-like consistency. In addition, iron phosphate is not volatile. In summary, the potential aggregate exposure, derived from oral, dermal and inhalation exposure should be minimal.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

A number of ecological effects toxicology data requirements are waived based on the known lack of toxicity of iron phosphate to birds, fish and non-target insects, its low solubility in water, conversion to less soluble form in the environment (soil), and its use pattern (soil application). Based on these factors, the data requirements for the toxicity studies in Mallard duck, rainbow trout, freshwater invertebrates, and

nontarget insect/honeybees are waived. The table below summarizes results of the studies that were performed.

Table 4

Guideline	Study	Results	MRID #
154-6	Avian Acute Oral - Bobwhite quail	LD_{50} and NOEL>2000 mg/kg; practically nontoxic.	440427-08
154-11	Nontarget Insect - ground beetle	No effect up to 2 times the maximum application rate.	441716-01
154-11	Nontarget Insect - ground beetle	No effect up to 2 times the maximum application rate.	441716-02
154-11	Nontarget - Earthworms	No effect up to 2 times the maximum application rate.	441716-03

2. Environmental Fate and Ground Water Data

Exposure assessments on this type of product (biochemical pesticide) are not performed unless human health or ecological effects issues arise in the toxicity studies for either of these disciplines (40 CFR §158.740(d)(2)(vi)). Since no endpoints of concern were identified, there is no requirement for environmental fate data.

3. Ecological Exposure and Risk Characterization

Exposure to daphnids and other aquatic invertebrates would not occur based on current label use directions. Exposure to honeybees is also not expected to occur, due to the composition of the end-use product (noodle-like material) and its use pattern (soil application). Nontarget insects, such as ground beetles and earthworms, could encounter the end-use product; however, in tests of rove beetles, ground beetles and earthworms, no effects were observed at up to twice the maximum application rate. Thus, the acute risk to aquatic invertebrates, nontarget insects, and earthworms is considered minimal to nonexistent.

D. EFFICACY DATA

No efficacy data were required to be submitted to the Agency since no public health uses are involved.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, iron phosphate is an effective biological molluscicide for the control of slubs and snails. Criteria "B" is satisfied by the current label and by the data presented in this document. It is believed that this new active ingredient will not cause any unreasonable adverse effects and does provide protection as claimed, satisfying Criteria "C". Criteria "D" is satisfied in that the toxicological properties of this product indicate that it is less toxic than other conventional pesticide products currently in use for this purpose.

Therefore, NEU 1165M Slug and Snail Bait is eligible for registration. The only uses are for terrestrial, non-commercial food crops (vegetables, berries, fruit trees, including citrus), domestic outdoor ornamentals, lawns, gardens, and non-commercial greenhouses. These are listed in Appendix A.

B. REGULATORY POSITION

1. Conditional/Unconditional Registration

All data requirements are fulfilled and the Biopesticides and Pollution Prevention Division recommends unconditional registration of NEU 1165M Slug and Snail Bait.

2. Tolerance Reassessment

There is no tolerance for the active ingredient, iron phosphate. A tolerance or exemption from tolerance is not applicable, due to the domestic, non-commercial uses of this product.

3. CODEX Harmonization

There is currently no Codex tolerance for iron phosphate or iron phosphate residues.

4. Non-food Registrations

There are no non-food issues at this time.

5. Risk Mitigation

Since there are no risk issues, no risk mitigation measures are required at this time for dietary risk, occupational and residential risk, risks to nontarget organisms (plants and wildlife), or ground and surface water contamination for this product.

6. Endangered Species Statement

Currently, the Agency is developing a program (Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and their habitats. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

Prior to the implementation of the Endangered Species Protection Program, the Agency will not impose specific labeling on those pesticides that pose risks to threatened and endangered species and their habitats but will defer imposing specific labeling language until the implementation of the program.

C. LABELING RATIONALE

1. Human Health Hazard

a. Worker Protection Standard

This product does not fall under the Worker Protection Standard (WPS); therefore, there are no human health hazard labeling issues associated with the WPS.

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for NEU 1165M Slug and Snail Bait, and concluded that the precautionary statements must be, "CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing." Exposure is expected to be minimal since the label directs that personal protective equipment (long sleeved-shirt, and long pants, shoes plus socks, and protective eyewear) must be worn.

d. Spray Drift Advisory

A spray drift advisory statement is not needed on the labeling for the registered uses of NEU 1165M Slug and Snail Bait, due to the composition of the end-use product and its domestic, non-commercial use pattern.

2. Environmental Hazards Labeling

Provided the following statement is placed into the environmental hazards statement, the risk of iron phosphate is minimal to nonexistent to nontarget organisms including endangered species:

"Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."

3. Application Rate

It is the Agency's position that the label for the pesticide products containing iron phosphate as the active ingredient complies with the current pesticide labeling requirements. The Agency has not required a maximum number of applications for the active ingredient.

D. LABELING

(1) Product name: **NEU 1165M Slug and Snail Bait**

Active Ingredient (by weight):

Iron Phosphate	1.0%
Inert Ingredients	99.9%
Total	100.0%

Signal word is "Caution," based on the eye irritation (toxicity category III). Use of an eye irritation statement is appropriate.

V. Actions Required by Registrants

Reporting adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity are required under 40 CFR Part 158.690(c), guideline reference number 152-16.

VI. Appendix A

The following table lists the use sites for the product. The label for the product is also attached.

NEU 1165M Slug and Snail Bait Non-commercial Use Sites - domestic garden or non-commercial vegetables including but not limited to artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes and turnips; non-commercial fruit including (but not limited to): apples, avocados, apricots, cherries, grapes, melons, peaches, plums, citrus, pears; non-commercial berries including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries; domestic or non-commercial outdoor ornamentals; domestic lawns; citrus groves; ivy patches and other ground cover; greenhouses.	Official Date: registered AUG 14 1997

NEU 1165M
SLUG AND SNAIL BAIT

Active Ingredient:	By weight
Iron phosphate	1.0%
Inert Ingredients:	99.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT 20 LBS

EPA registration #67702- **EPA establishment #67702-WG-1**

STATEMENT OF PRACTICAL TREATMENT
If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals: Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Environmental Hazards: For terrestrial uses. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

The slugs and snails controlled by this product include (but are not limited to): *Deroceras reticulatum* (Field slug), *Deroceras laeve* (Smooth slug), *Arion subfuscus* (Dusky slug), *Arion circumscriptus* (Gray garden slug), *Arion hortensis* (Black field slug), *Arion rufus* (Large red slug), *Arion ater* (Large black slug), *Limax flavus* (Spotted garden slug), *Limax tenellus* (Slender slug), *Ariolimax columbianus* (Banana slug), *Helix* spp., spp., *Helicella* spp., and *Cepaea* spp.

Home And Garden

HOW TO APPLY: The slug and snail bait granules should be scattered on the soil around or near the plants to be protected in domestic garden plots. Apply bait evenly at approximately 1 lb. per 1000 square feet (0.15 oz., or about 1 level tablespoon, per square yard) and reapply as the bait is consumed or at least every two weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The soil should be moist but with little or no standing water.

Reapply as the bait is consumed or at least every two weeks. Apply more heavily if the infestation is severe, if the area is heavily watered or after long periods of heavy rain. See specific directions for different plant types and for inside non-commercial greenhouses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

WHERE TO APPLY: All likely areas of infestation should be treated, especially around the perimeter of domestic garden plots because these pests travel into plant areas from daytime refuges. They favor damp places around vegetable plants such as beans, tomatoes, lettuce, cabbage, celery and squash. Other favorite areas are domestic flower gardens, rockeries, hedges, dichondra lawns, non-commercial citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

Non-Commercial Vegetables

The bait can be used to protect any domestic garden (or non-commercial) vegetables from slug and snail damage, including (but not limited to): artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes and turnips. Scatter the bait around the perimeter of the vegetable plot at approximately 1 lb. per 1000 square feet to provide a protective "barrier" for slugs entering the garden plot. If slugs or snails are inside the rows, then scatter the bait on the soil around the base of the plants and between the rows.

Non-Commercial Fruits Including Citrus

The bait can be used to protect non-commercial fruits from slugs and snails, including (but not limited to): apples, avocados, apricots, cherries, grapes, melons, peaches, plums, citrus, pears. For seedlings spread the bait around the base of the stem. Apply at 0.15 oz., or 1 level tablespoon, per square yard, in a 6 inch circular band around the base of the plants to be protected. For older

trees, spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders.

Non-Commercial Berries

The bait can be used to protect non-commercial berries from slugs and snails, including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries. Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Domestic or Non-Commercial Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at 0.15 oz., or 1 level tablespoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamentals and the grass. Slugs traveling to the plants will encounter the bait before reaching the plant. Scatter the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs traveling to the plot.

Non-Commercial Greenhouses

Where snails are a problem in non-commercial greenhouses, scatter the bait in the plant pots of plants being damaged or around pots on greenhouse benches. Apply about ½ teaspoon per 9 inch pot.

Domestic Lawns

The bait can be used to protect lawns. When slugs or snails are detected, scatter the bait at a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with a granular spreader where the slugs or snails are observed.

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

CONTAINER DISPOSAL: Do not reuse container. Securely wrap original container in several layers of newspaper and discard in trash.

WARRANTY

Seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with directions under normal use conditions. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. Buyer assumes all risk of any such use. Seller makes no other warranties, either expressed or implied.

[The following claims and product information may be presented on the product's label or labeling:
-**NOTE**: This package is sold by weight. Contents may have settled during shipment.
-US Patent number 5,437,870.
-This container is made from XX% recycled materials.]

GENERAL INFORMATION (WHY SLUG AND SNAIL BAIT IS SO EFFECTIVE)

This product is a unique blend of an iron phosphate active ingredient, originating from soil, with slug and snail bait additives. It is used as an ingredient in fertilizers. The bait which is not ingested by snails and slugs will degrade and become part of the soil in your garden.

The bait is extremely (highly) attractive to slugs and snails and lures them from their hiding places and plants. Ingestion, even in small amounts, will cause them to cease feeding. This physiological effect of the bait gives immediate protection to the plants even though the slugs and snails may remain in the area. After eating the bait, the slugs and snails cease feeding, become less mobile and begin to die within three to six days. Dead slugs and snails may not be visible as they often crawl away to secluded places to die. Plant protection will be observed in the dramatic decrease in plant damage.

This product is effective against a wide variety of slugs and snails and will give protection to home lawns, gardens, greenhouses, outdoor ornamentals, vegetable gardens, fruits, berries, citrus and crop plants. The bait can be scattered on the lawn or on the soil around any vegetable plants, flowers or fruit trees or bushes to be protected.

Registrant: W. Neudorff GmbH KG, Postfach 1209, an der Mühle 3,
D-31860 Emmerthal, Germany

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7501W) 401 M St., S.W.
Washington, D.C. 20460

EPA Reg. Number: 67702-3

Date of Issuance: AUG 14 1997

NOTICE OF PESTICIDE:
__X__ Registration
_____ Reregistration

(under FIFRA, as amended)

Term of Issuance: Unconditional

Name of Pesticide Product: NEU 1165M Slug and Snail Bait

Name and Address of Registrant (include ZIP Code):
W. Neudorff GmbH KG
c/o Walter G. Talarek, P.C.
1008 Riva Ridge Drive
Great Falls, VA 22066

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label change:

   a. Revise the EPA Registration Number to read, "EPA Reg. No. 67702-3."

3. Submit five copies of the revised final printed label for the record.

Signature of Approving Official: Janet L. Anderson

Date: AUG 14 1997

EPA Form 8570-6

NEU 1165M
SLUG AND SNAIL BAIT

ACCEPTED
AUG 14 1997
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 67702-3

Active Ingredient:	By weight
Iron phosphate	1.0%
Inert Ingredients:	99.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT 20 LBS

EPA registration #67702- **EPA establishment #67702-WG-1**

STATEMENT OF PRACTICAL TREATMENT
If in eyes: Flush eyes with plenty of water. Call a physician if irritation persists.

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals: Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Environmental Hazards: For terrestrial uses. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

The slugs and snails controlled by this product include (but are not limited to): *Deroceras reticulatum* (Field slug), *Deroceras laeve* (Smooth slug), *Arion subfuscus* (Dusky slug), *Arion circumscriptus* (Gray garden slug), *Arion hortensis* (Black field slug), *Arion rufus* (Large red slug), *Arion ater* (Large black slug), *Limax flavus* (Spotted garden slug), *Limax tenellus* (Slender slug), *Ariolimax columbianus* (Banana slug), *Helix* spp., spp., *Helicella* spp., and *Cepaea* spp.

Home And Garden

HOW TO APPLY: The slug and snail bait granules should be scattered on the soil around or near the plants to be protected in domestic garden plots. Apply bait evenly at approximately 1 lb. per 1000 square feet (0.15 oz., or about 1 level tablespoon, per square yard) and reapply as the bait is consumed or at least every two weeks. Do not place in piles. If the ground is dry, wet it before applying bait. The soil should be moist but with little or no standing water.

Reapply as the bait is consumed or at least every two weeks. Apply more heavily if the infestation is severe, if the area is heavily watered or after long periods of heavy rain. See specific directions for different plant types and for inside non-commercial greenhouses.

WHEN TO APPLY: Evening is the best time to apply the bait, as slugs and snails travel and feed mostly by night or early morning.

WHERE TO APPLY: All likely areas of infestation should be treated, especially around the perimeter of domestic garden plots because these pests travel into plant areas from daytime refuges. They favor damp places around vegetable plants such as beans, tomatoes, lettuce, cabbage, celery and squash. Other favorite areas are domestic flower gardens, rockeries, hedges, dichondra lawns, non-commercial citrus groves, ivy patches, and other ground cover where they obtain shelter by day.

Non-Commercial Vegetables

The bait can be used to protect any domestic garden (or non-commercial) vegetables from slug and snail damage, including (but not limited to): artichokes, asparagus, beans, beets, blackeyed peas, broccoli, Brussels sprouts, cabbage, cantaloupe, carrots, cauliflower, corn, cucumbers, eggplants, garlic, lettuce, onions, peas, peppers, potatoes, radishes, rutabagas, spinach, squash, Swiss chard, tomatoes and turnips. Scatter the bait around the perimeter of the vegetable plot at approximately 1 lb. per 1000 square feet to provide a protective "barrier" for slugs entering the garden plot. If slugs or snails are inside the rows, then scatter the bait on the soil around the base of the plants and between the rows.

Non-Commercial Fruits Including Citrus

The bait can be used to protect non-commercial fruits from slugs and snails, including (but not limited to): apples, avocados, apricots, cherries, grapes, melons, peaches, plums, citrus, pears. For seedlings spread the bait around the base of the stem. Apply at 0.15 oz., or 1 level tablespoon, per square yard, in a 6 inch circular band around the base of the plants to be protected. For older

trees, spread the bait around the base of the tree to intercept slugs and snails traveling to the trunk. Apply the bait at approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders.

Non-Commercial Berries

The bait can be used to protect non-commercial berries from slugs and snails, including (but not limited to): strawberries, blackberries, blueberries, boysenberries, loganberries, raspberries. Spread the bait around the perimeter of the plot to intercept slugs and snails migrating toward the berries. Use a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with granular spreaders. If slugs and snails are already in the plots, then carefully spread bait between the furrows near the base of the plants. For small plots, treat around the base of the plants to be protected. Do not spread over the entire area but apply selectively.

Domestic or Non-Commercial Outdoor Ornamentals

Scatter bait in a 6 inch circular band around the base of the plants to be protected at 0.15 oz., or 1 level tablespoon, per square yard. If plants are next to a grassy area, spread the bait between the ornamentals and the grass. Slugs traveling to the plants will encounter the bait before reaching the plant. Scatter the bait around the perimeter of the plot at approximately 1 lb. per 1000 square feet to intercept snails and slugs traveling to the plot.

Non-Commercial Greenhouses

Where snails are a problem in non-commercial greenhouses, scatter the bait in the plant pots of plants being damaged or around pots on greenhouse benches. Apply about ½ teaspoon per 9 inch pot.

Domestic Lawns

The bait can be used to protect lawns. When slugs or snails are detected, scatter the bait at a rate of approximately 1 lb. per 1000 square feet and scatter by hand or with a granular spreader where the slugs or snails are observed.

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store this product in its original container and keep in a secure storage area out of reach of children and domestic animals.

CONTAINER DISPOSAL: Do not reuse container. Securely wrap original container in several layers of newspaper and discard in trash.

WARRANTY

Seller warrants that this product conforms to the chemical description on this label and is reasonably fit for purposes stated on this label only when used in accordance with directions under normal use conditions. This warranty does not extend to use of this product contrary to label directions, or under abnormal use conditions, or under conditions not reasonably foreseeable to seller. Buyer assumes all risk of any such use. Seller makes no other warranties, either expressed or implied.

[The following claims and product information may be presented on the product's label or labeling:

-**NOTE**: This package is sold by weight. Contents may have settled during shipment.

-US Patent number 5,437,870.

-This container is made from XX% recycled materials.]

GENERAL INFORMATION (WHY SLUG AND SNAIL BAIT IS SO EFFECTIVE)

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